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Marcia Rossell
Type or print name

Marcia Rossell
Signature

April 7, 2003
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**RECEIVED
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DEC 01 2003

IN RE APPLICATION OF

Confirmation No. 4496

CHENG, ET AL.

Art Unit: 1636

APPLICATION NO: 10/081,969

Examiner: Marvich, Maria

FILED: FEBRUARY 22, 2002

Atty. Docket: 4-31704A

FOR: NOVEL ONCOLYTIC ADENOVIRAL VECTORS

OFFICIAL

U.S. Patent & Trademark Office
P.O. Box 2327
Arlington, Virginia 22202

TRANSMITTAL LETTER

Sir:

Enclosed please find the following:

- a. Information Disclosure Statement (1 page);
- b. PTO Form 1449 (20 pages) with cited references;
- c. Fee Letter for Information Disclosure Statement;
- d. Fee Transmittal Sheet; and
- e. Return postcard.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Bldg. 430
East Hanover, NJ 07936-1080
(301) 258-4832

Douglas Golightly
Douglas Golightly
Patent Agent
Reg. No. 51,244

Date: April 7, 2003

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FOR: NOVEL ONCOLYTIC ADENOVIRAL VECTORS

U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202INFORMATION DISCLOSURE STATEMENT

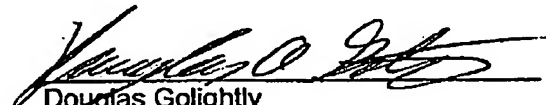
Sir:

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. §1.97(c).
A letter for payment of fee set forth in 37 C.F.R. §1.17(p) is enclosed.

In accordance with 37 C.F.R. §1.56, applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449. Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Novartis
Corporate Intellectual Property
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East Hanover, NJ 07936-1080
(301) 258-4832
Douglas Golightly
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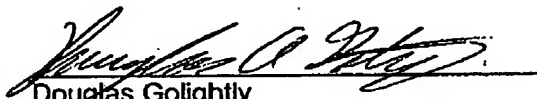
FEE LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Please charge Deposit Account No. 19-0134 in the name of Novartis Corporation in the amount of \$180 for payment of the fee pursuant to 37 CFR §1.17(p) for the submission of an Information Disclosure Statement under 37 CFR §1.97(c). The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Bldg. 430
East Hanover, NJ 07936-1080
(301) 258-4832


Douglas Golightly
Patent Agent
Reg. No. 51,244

Date: April 7, 2003

Sheet 1 of 20

FORM PTO-1449
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.
4-31704A
APPLICATION NO.
10/081,969
APPLICANT
Ennist, et al.
FILING DATE
FEBRUARY 22, 2002

Group

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|------------------------|-------|----------|-------------|
| | AA | 10/081,961 | 2/22/02 | Gorziglia, et al. | | | |
| | AB | 2001/0006633A1 | 7/5/01 | Kirn, D. | | | |
| | AC | 5,672,344 | 9/30/97 | Kelley, et al. | | | |
| | AD | 5,677,178 | 10/14/97 | McCormick, F. | | | |
| | AE | 5,698,443 | 12/16/97 | Henderson, et al. | | | |
| | AF | 5,707,618 | 1/13/98 | Armentano, et al. | | | |
| | AG | 5,830,686 | 11/3/98 | Henderon, D. | | | |
| | AH | 5,837,511 | 11/17/98 | Falck-Pederson, et al. | | | |
| | AI | 5,871,726 | 2/16/99 | Henderson, et al. | | | |
| | AJ | 5,994,128 | 11/30/99 | Fallaux, et al. | | | |
| | AK | 5,998,205 | 12/7/99 | Hellenbeck, et al. | | | |
| | AL | 6,057,299 | 5/2/00 | Henderson, D. | | | |

FOREIGN PATENT DOCUMENTS

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| | AQ | WO 00/31286 | 6/2/00 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| | | |
|--|----|---|
| | AR | Adams, et al., "Transcriptional Control by E2F," <i>Seminars in Cancer Biology</i> , 6:99-108 (1995) |
| | AS | Albert, et al., "Dendritic Cells Acquire Antigen From Apoptotic Cells and Induce Class I-restricted CTLs," <i>Nature</i> , 392:86-89 (March 1998) |
| | AT | Alemany, et al., "Replicative Adenoviruses for Cancer Therapy," <i>Nature Biotechnology</i> , 18:723-727 (July 2000) |

EXAMINER

DATE CONSIDERED

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Sheet 2 of 20

FORM PTO-1449
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE
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APPLICATION NO.
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Ennist, et al.
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U.S. PATENT DOCUMENTS

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|---------------------|----|-----------------|----------|-------------------|-------|----------|----------------|
| | AA | 6,136,792 | 10/24/00 | Henderson, D. | | | |
| | AB | 6,197,293 B1 | 3/6/01 | Henderson, et al. | | | |
| | AC | 6,254,862 B1 | 7/3/01 | Little, et al. | | | |
| | AD | 6,271,207 B1 | 8/7/01 | Cristiano, et al. | | | |
| | AE | 6,297,219 B1 | 10/2/01 | Nabel, et al. | | | |
| | AF | 6,432,700 B1 | 8/13/02 | Henderson, et al. | | | |
| | AG | 6,436,394 B1 | 8/20/02 | Henderson, et al. | | | |
| | AH | 6,495,130 B1 | 12/17/02 | Henderson, et al. | | | |
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FOREIGN PATENT DOCUMENTS

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| | AQ | WO 00/67576 | 11/16/00 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

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| | AR | Altmann, et al., "Epothilones and Related Structures -- a New Class of Microtubule Inhibitors with Potent In Vivo Antitumor Activity," <i>Biochemica et Biophysica Acta</i> , 1470:M79-M91 (2000) |
| | AS | Angelichio, et al., "Comparison of Several Promoters and Polyadenylation Signals for Use in Heterologous Gene Expression in Cultured Drosophila Cells," <i>Nucleic Acids Research</i> , 19(18):5037-5043 (1991) |
| | AT | Armitage, J., "Emerging Applications of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," <i>Blood</i> , 92(12):4491-4508 (December 15, 1998) |

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Sheet 3 of 20

FORM PTO-1449
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| | AQ | WO 01/23004 | 4/5/01 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| | | |
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| | AR | Armstrong, et al., "Antitumor Effects of Granulocyte-Macrophage Colony-Stimulating Factor Production by Melanoma Cells," <i>Cancer Research</i> , 56:2191-2198 (May 1, 1996) |
| | AS | Axelrod, et al., "A Novel Oncolytic Adenovirus Encoding an IL-6/sIL-6R Fusion Protein," Abstract No. P6, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
| | AT | Babiss, et al., "Cellular Promoters Incorporated into the Adenovirus Genome: Effects of Viral Regulatory Elements on Transcription Rates and Cell Specificity of Albumin and β -Globin Promoters," <i>Molecular and Cellular Biology</i> , 6(11):3798-3806 (November 1986) |

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Sheet 4 of 20

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| | AM | WO 01/36650 | 5/25/01 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AN | WO 01/72341 | 10/4/01 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AO | WO 01/73093 | 10/4/01 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AP | WO 02/068627 | 9/6/02 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AQ | WO 94/18992 | 9/1/94 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

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| AR | Benedict, et al., "Three Adenovirus E3 Proteins Cooperate to Evade Apoptosis by Tumor Necrosis Factor-related Apoptosis-inducing Ligand Receptor-1 and -2," <i>The Journal of Biological Chemistry</i> , 276(5):3270-3278 (February 2, 2001) |
| AS | Bergsland, et al., "Shedding Old Paradigms: Developing Viruses to Treat Cancer," <i>Journal of Clinical Oncology</i> , 20(9):2220-2222 (May 1, 2002) |
| AT | Bert, et al., "Generation of an Improved Luciferase Reporter Gene Plasmid That Employs a Novel Mechanism for High-Copy Replication," <i>Plasmid</i> , 44:173-182 (September 2000) |

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| | AN | WO 96/34969 | 11/7/96 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AO | WO 97/01358 | 1/16/97 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
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| | AQ | WO 97/48277 | 12/24/97 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

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| | AR | Black, et al., "Regulation of E2F: A Family of Transcription Factors Involved in Proliferation Control," <i>Gene</i> , 237:281-302 (1999) |
| | AS | Boon, et al., "Cancer Tumor Antigens," <i>Current Opinion in Immunology</i> , 9:681-683 (1997) |
| | AT | Bouvet, et al., "Suppression of the Immune Response to an Adenovirus Vector and Enhancement of Intratumoral Transgene Expression by Low-Dose Etoposide," <i>Gene Therapy</i> , 5:189-195 (1998) |

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| | AO | WO 98/28469 | 7/2/98 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AP | WO 98/35028 | 8/13/98 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AQ | WO 98/39464 | 9/11/98 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

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| AR | Bristol, et al., "GM-CSF Containing Oncolytic Adenoviruses for the Treatment of Cancer," Abstract No. P2, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
| AS | Bristol, et al., "GM-CSF Containing Oncolytic Adenoviruses for the Treatment of Cancer," poster presented at <i>The 10th Annual Meeting of the European Society of Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
| AT | Bristol, et al., "GM-CSF Mediated Stimulation of Innate Anti-tumor Responses," poster presented at the <i>Keystone Symposia, Basic Aspects of Tumor Immunology</i> , February 17-23, 2003 |

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| | AO | WO 98/39467 | 9/11/98 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AP | WO 99/06576 | 2/11/99 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AQ | WO 99/28469 | 6/10/99 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| | |
|----|--|
| AR | Bristol, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," <i>American Society for Gene Therapy, 5th Annual Meeting</i> , June 5-9, 2002; poster presented June 6, 2002 |
| AS | Bristol, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," <i>Molecular Therapy</i> , 5(5):abstract No. 311 (May 2002) |
| AT | Bruder, et al., "Nuclear Factor EF-1A Binds to the Adenovirus E1A Core Enhancer Element and to Other Transcriptional Control Regions," <i>Molecular and Cellular Biology</i> , 9(11):5143-5153 (November 1989) |

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U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|------|------|-------|----------|----------------|
| | AA | | | | | | |
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FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION | |
|--|----|-----------------|----------|--------|-------|----------|--------------------------|--------------------------|
| | | | | | | | YES | NO |
| | AM | WO 99/55831 | 11/4/99 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AN | WO 99/59604 | 11/25/99 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AO | WO 92/03563 | 3/5/92 | WIPO | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AP | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AQ | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |

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| AR | Bryan, et al., "Evidence for an Alternative Mechanism for Maintaining Telomere Length in Human Tumors and Tumor-derived Cell Lines," <i>Nature Medicine</i> , 3(11):1271-1274 (November 1997) |
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| AT | Chao, et al., "Assembly of the Cleavage and Polyadenylation Apparatus Requires About 10 Seconds In Vivo and Is Faster for Strong Than for Weak Poly(A) Sites," <i>Molecular and Cellular Biology</i> , 19(8):5588-5600 (August 1999) |

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| AC | Chia, et al., "A Novel Conditionally Oncolytic Adenovirus for the Treatment of Nasopharyngeal Carcinoma (NPC)," <i>Proceedings of the American Association for Cancer Research</i> , 43:1098-1099, abstract No. 5441 (March 2002) |
| AD | Chiocca, E., "Oncolytic Viruses," <i>Nature</i> , 2:938-950 (December 2002) |
| AE | Christ, et al., "Modulation of the Inflammatory Properties and Hepatotoxicity of Recombinant Adenovirus Vectors by the Viral E4 Gene Products," <i>Human Gene Therapy</i> , 11:415-427 (February 10, 2000) |
| AF | Colgan, et al., "Mechanism and Regulation of mRNA Polyadenylation," <i>Genes and Development</i> , 11:2755-2766 (1997) |
| AG | Curiel, et al., "Strategies to Improve the Therapeutic Utility of Conditionally Replicative Adenoviruses (CRAds) for Cancer Therapy," <i>Proceedings of the American Association for Cancer Research</i> , 43:662, abstract No. 3287 (March 2002) |
| AH | Demers, et al., "Antitumor Efficacy and Replication of an Oncolytic Adenovirus, 01/PEME, in Tumor Tissue Following Intravenous Administration," <i>Proceedings of the American Association for Cancer Research</i> , 43:663, abstract No. 3291 (March 2002) |
| AI | Denome, et al., "Patterns of Polyadenylation Site Selection in Gene Constructs Containing Multiple Polyadenylation Signals," <i>Molecular and Cellular Biology</i> , 8(11):4829-4839 (November 1988) |
| AJ | DeWeese, et al., "A Phase I Trial of CV706, a Replication-Competent, PSA Selective Oncolytic Adenovirus, for the Treatment of Locally Recurrent Prostate Cancer Following Radiation Therapy," <i>Cancer Research</i> , 61:7464-7472 (October 15, 2001) |
| AK | Dong, et al., "Angiostatin-Mediated Suppression of Cancer Metastases by Primary Neoplasms Engineered to Produce Granulocyte/Macrophage Colony-Stimulating Factor," <i>J. Exp. Med.</i> , 188(4):755-763 (August 17, 1998) |
| AL | Dong, et al., "Macrophage-Derived Metalloelastase is Responsible for the Generation of Angiostatin in Lewis Lung Carcinoma," <i>Cell</i> , 88:801-810 (March 21, 1997) |
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| AB | Duque, et al., "Adenovirus Lacking the 19-kDa and 55-kDa E1B Genes Exerts a Marked Cytotoxic Effect in Human Malignant Cells," <i>Cancer Gene Therapy</i> , 6(6):554-563 (1999) |
| AC | Dyson, N., "The Regulation of E2F by pRB-family Proteins," <i>Genes and Development</i> , 12:2245-2262 (August 1998) |
| AD | Emens, et al., "Chemotherapy: Friend or Foe to Cancer Vaccines?" Current Opinion in <i>Molecular Therapeutics</i> , 3(1):77-84 (February 2001) |
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| AH | Ennist, et al., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," <i>Proceedings of the American Association for Cancer Research</i> , 43:1098, abstract No. 5437 (March 2002) |
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| AK | Fan, et al., "Efficient Gene Delivery into Human Primary Glioma Cells by Fiber Retargeted Adenoviral Vectors: Implications for In Vivo Gene Delivery into Malignant Gliomas," Abstract No. P7, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
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| AG | Habib, et al., "E1B-Deleted Adenovirus (dl1520) Gene Therapy for Patients with Primary and Secondary Liver Tumors," <i>Human Gene Therapy</i> , 12:219-226 (February 10, 2001) |
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| AJ | Hallenbeck, et al., "Oncolytic Adenoviruses Dependent Upon Two Prevalent Alterations in Human Cancer; Disregulation of the RB-Pathway and Telomerase," <i>Molecular Therapy</i> , 5(5):Abstract 165 (May 2002) |
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| AB | Hearing, et al., "The Adenovirus Type 5 E1A Transcriptional Control Region Contains a Duplicated Enhancer Element," <i>Cell</i> , 33:695-703 (1983) |
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| AF | Heise, et al., "Replication-Selective Adenoviruses as Oncolytic Agents," <i>The Journal of Clinical Investigation</i> , 105(7):847-851 (April 2000) |
| AG | Hermiston, T., "Gene Delivery From Replication-Selective Viruses: Arming Guided Missiles in the War Against Cancer," <i>The Journal of Clinical Investigation</i> , 105(9):1169-1172 (May 2000) |
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| AJ | Horwitz, M., "Adenovirus Immunoregulatory Genes and Their Cellular Targets," <i>Virology</i> , 279:1-8 (January 5, 2001) |
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| AH | Johnson, et al., "Autoregulatory Control of E2F1 Expression in Response to Positive and Negative Regulators of Cell Cycle Progression," <i>Genes and Development</i> , 8:1514-1525 (1994) |
| AI | Johnson, et al., "Cytosine Deaminase-armed Selectively Replicating Adenovirus for the Treatment of Cancer," <i>Proceedings of the American Association for Cancer Research</i> , 43:656, abstract No. 3257 (March 2002) |
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| AB | Kirn, D., "Clinical Research Results with dl1520 (Onyx-015), a Replication-selective Adenovirus for the Treatment of Cancer: What Have We Learned?" <i>Gene Therapy</i> , 8:89-98 (January 2001) |
| AC | Kirn, D., "Replication-selective Microbiological Agents: Fighting Cancer With Targeted Germ Warfare," <i>The Journal of Clinical Investigation</i> , 105(7):837-839 (April 2000) |
| AD | Kirn, D., "Replication-selective Oncolytic Adenoviruses: Virotherapy Aimed at Genetic Targets in Cancer," <i>Oncogene</i> , 19:6660-6669 (December 27, 2000) |
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| AF | Kirn, et al., "ONYX-015: Clinical Data are Encouraging," <i>Nature Medicine</i> , 4(12):1341-1342 (December 1998) |
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| AB | Li, et al., "Replication Competent Oncolytic Adenovirus for Colon Cancer Therapy," <i>Proceedings of the American Association for Cancer Research</i> , 43:858, abstract No. 4251 (March 2002) |
| AC | Limbach, et al., "Development of Adenovirus Serotype 35 as a Gene Transfer Vector," poster presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
| AD | Liu, et al., "Optimised Oncolytic Herpes Simplex Virus for Cancer Treatment," Abstract No. Or33, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002 |
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